

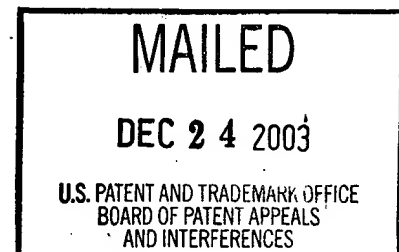
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte HSUAN-YIN LAN-HARGEST,
ROBERT J. KAUFMAN, and NORBERT L. WIECH

Appeal No. 2003-2139
Application No. 09/812,945

ON BRIEF



Before WINTERS, SCHEINER, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the
examiner's final rejection of claims 1, 2, 4-7, 10, 12, 17, 18, 40-46, which are all
the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced in
the attached appendix.

The references relied upon by the examiner are:

Richon et al. (Richon), "A class of hybrid polar inducers of transformed cell
differentiation inhibits histone deacetylases," Proc. Natl. Acad. Sci. U.S.A., Vol.
95, No. 6, PubMed Abstract (1998)

Marks et al. (Marks), "Histone Deacetylase Inhibitors: Inducers of Differentiation or Apoptosis of Transformed Cells," J. National Cancer Institute, Vol. 92, No. 15, pp. 1210-16 (2000)

GROUND OF REJECTION

Initially, we note from a review of Paper No. 4, mailed November 6, 2001 that the examiner required appellants to elect a single disclosed invention, and a single disclosed species of (a) compound, and (b) disorder, for prosecution on the merits. Appellants, in turn, elected the invention defined by claims 1-46, 7-phenyl-2,4,6-hepta-trienoylhydroxamic acid as the elected compound, and cancer as the elected disorder. See Paper No. 4, bridging paragraph, pages 3-4; Paper No. 5, page 1. Accordingly, we limit our consideration of this record to appellants' elected species, and we take no position respecting the patentability of appellants' claimed method as it may relate to the remaining, non-elected species. Cf. Ex parte Ohsaka, 2 USPQ2d 1460 (BPAI 1987).

Claims 1, 2, 4-7, 10, 12, 17, 18, 40-46 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the full scope of the claimed invention.

Claims 1, 2, 4-7, 10, 12, 17, 18, 40-46 stand rejected under 35 U.S.C. § 103 as being unpatentable over Richon and Marks.

We reverse.

CLAIM CONSTRUCTION

With reference to Texas Instruments Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1172, 26 USPQ2d 1018, 1023-1024 (Fed. Cir. 1993), appellants argue:

The treatment described in the "thereby" clause of claim 1 is the result of contacting cells with an effective amount of a compound of formula (I). The recitation of treatment as the result obtained by contacting cells with an effective amount of a compound of formula (I) does not change the scope of the invention otherwise defined by claim 1. The treatment of a disorder, and the identity of the disorder, is not the invention being claimed.

The claimed method comprises two steps: (1) contacting cells with an effective amount of a compound of formula (I); and (2) determining whether the level of acetylated histones in the treated cells is higher than in untreated cells under the same conditions. As explained by the examiner (Answer, page 5), "[c]onstruing the claims in light of appellant [sic] arguments would lead the [s]killed [a]rtisan to understand and practice the instant method as a screening method, i.e., a method of assaying compounds of formula I to measure their histone deacetylation inhibitory effect." In contrast, the examiner finds (id.), "[r]eading the claim in its entirety and including the phrase 'thereby treating one or more disorders' in the claim language, leads the skilled artisan to understand and practice the instant invention as a method of treating histone deacetylase mediated disorders in general and cancer (the elected disorder), in particular."

As set forth in Texas Instruments, “[a] ‘whereby’ clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim.” In contrast, the clause in claim 1 requires the additional treatment of one or more disorders mediated by histone deacetylase. Claim 1 requires an effective amount of a compound of formula 1 to (1) inhibit histone deacetylase in cells and (2) treat one or more disorders mediated by histone deacetylase. Stated differently, we consider the clause “thereby treating one or more disorders mediated by histone deacetylase” to add to the patentability and substance of the claim.

DISCUSSION

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

According to the examiner (Answer, page 3), “while being enabling for some types of cancer, [appellants’ specification] does not reasonably provide enablement for ‘treating cancer’ in general.” While the examiner offers no evidence in support of his position, the examiner finds (*id.*) “[g]iven the current state of the art, the treatment of all cancers broadly is unpredictable. One of ordinary skill in the art would not believe that one compound could treat all types of cancer...” According to appellants (Brief, page 3), “[t]he error in this rejection stems from an erroneous interpretation of the clause ‘thereby treating one or more disorders’ of independent claim 1.” For the foregoing reasons we are not persuaded by this argument.

However, having found that the clause "thereby treating one or more disorders mediated by histone deacetylase" is a positive limitation on appellants' claimed invention, we find that the cancer to be treated must be one that is mediated by histone deacetylase. Therefore, contrary to the examiner's position, the claimed invention is not drawn to the treatment of all types of cancer, instead the claimed invention is drawn to the treatment of cancer mediated by histone deacetylase. Since the examiner has not presented any evidence or argument as to why the specification does not provide an enabling description of the treatment of cancer mediated by histone deacetylase we are compelled to reverse the rejection of claims 1, 2, 4-7, 10, 12, 17, 18, 40-46 under 35 U.S.C. § 112, first paragraph.

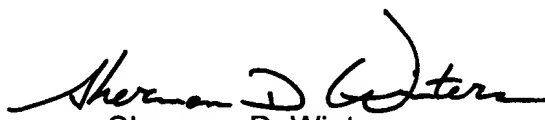


THE REJECTION UNDER 35 U.S.C. § 103:

According to the examiner (Answer, page 4), Richon "teaches that hydroxamic acid derivatives, a class of hybrid bipolar compounds (HPCs) induce terminal differentiation and[/]or apoptosis in various transformed cells... [and Marks] teaches that hydroxamic acid-based HPCs are potentially effective agents for cancer therapy...." While noting (id.) that neither Richon nor Marks "explicitly teach the elected compound in their method of treating cancer," the examiner finds "[i]t would have been obvious ... to employ the elected compound in a method of treating cancer ... because the elected compound is a hydroxamic acid derivative." The basis for the examiner's rejection is perhaps more succinctly stated on page 7 of the Answer, Marks "provides a guide in choosing hydroxamic acid derivatives that would exhibit ... therapeutic activities."

On this record, the examiner did not provide the factual evidence necessary to establish that either reference discloses or suggests the elected species that is a requirement of every claim.

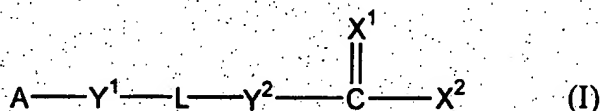
Accordingly, we reverse the rejection of claims 1, 2, 4-7, 10, 12, 17, 18, and 40-46 under 35 U.S.C. § 103 as being unpatentable over Richon and Marks.

REVERSED

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Sherman D. Winters)	
Administrative Patent Judge)	
)	
)	BOARD OF PATENT
Toni R. Scheiner)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
Donald E. Adams)	
Administrative Patent Judge)	

Appendix

1. A method of inhibiting histone deacetylation activity in cells comprising contacting the cells with an effective amount of a compound of formula (I), thereby treating one or more disorders mediated by histone deacetylase; said compound having the following formula:



wherein

A is a cyclic moiety selected from the group consisting of C₃₋₁₄ cycloalkyl, 3-14 membered heterocycloalkyl, C₄₋₁₄ cycloalkenyl, 3-8 membered heterocycloalkenyl, aryl, or heteroaryl; the cyclic moiety being optionally substituted with alkyl, alkenyl, alkynyl, alkoxy, hydroxyl, hydroxylalkyl, halo, haloalkyl, amino, alkylcarbonyloxy, alkyloxycarbonyl, alkylcarbonyl, alkylsulfonylamino, aminosulfonyl, or alkylsulfonyl; or A is a saturated branched C₃₋₁₂ hydrocarbon chain or an unsaturated branched C₃₋₁₂ hydrocarbon chain optionally interrupted by -O-, -S-, -N(R^a)-, -C(O)-, -N(R^a)-SO₂-, -SO₂-N(R^a)-, -N(R^a)-C(O)-O-, -O-C(O)-N(R^a)-, -N(R^a)-C(O)-N(R^b)-, -O-C(O)-, -C(O)-O-, -O-SO₂-, -SO₂-O-, or -O-C(O)-O-, where each of R^a and R^b, independently, is hydrogen, alkyl, alkenyl, alkynyl, alkoxy, hydroxylalkyl, hydroxyl, or haloalkyl; each of the saturated and the unsaturated branched hydrocarbon chain being optionally substituted with alkyl, alkenyl, alkynyl, alkoxy, hydroxyl, hydroxylalkyl, halo, haloalkyl, amino, alkylcarbonyloxy, alkyloxycarbonyl, alkylcarbonyl, alkylsulfonylamino, aminosulfonyl, or alkylsulfonyl;

each of Y¹ and Y², independently, is -CH₂-, -O-, -S-, -N(R^c)-, -N(R^c)-C(O)-O-, -O-C(O)-N(R^c)-, -N(R^c)-C(O)-N(R^d)-, -O-C(O)-O-, or a bond; each of R^c and R^d, independently, being hydrogen, alkyl, alkenyl, alkynyl, alkoxy, hydroxylalkyl, hydroxyl, or haloalkyl;

L is a straight C₂₋₁₂ hydrocarbon chain optionally containing at least one double bond, at least one triple bond, or at least one double bond and one triple bond; said hydrocarbon chain being optionally substituted with C₁₋₄ alkyl, C₂₋₄ alkenyl, C₂₋₄ alkynyl, C₁₋₄ alkoxy, hydroxyl,

halo, amino, nitro, cyano, C₃₋₅ cycloalkyl, 3-5 membered heterocycloalkyl, monocyclic aryl, 5-6 membered heteroaryl, C₁₋₄ alkylcarbonyloxy, C₁₋₄ alkyloxycarbonyl, C₁₋₄ alkylcarbonyl, or formyl; and further being optionally interrupted by -O-, -N(R^e)-, -N(R^e)-C(O)-O-, -O-C(O)-N(R^e)-, -N(R^e)-C(O)-N(R^f)-, or -O-C(O)-O-; each of R^e and R^f, independently, being hydrogen, alkyl, alkenyl, alkynyl, alkoxy, hydroxylalkyl, hydroxyl, or haloalkyl;

X¹ is O or S; and

X² is -OR¹, -SR¹, -NR³-OR¹, -NR³-SR¹, -C(O)-OR¹, -CHR⁴-OR¹, -N=N-C(O)-N(R³)₂, or -O-CHR⁴-O-C(O)-R⁵, where each of R¹ and R², independently, is hydrogen, alkyl, hydroxylalkyl, haloalkyl, or a hydroxyl protecting group; R³ is hydrogen, alkyl, alkenyl, alkynyl, alkoxy, hydroxylalkyl, hydroxyl, haloalkyl, or an amino protecting group; R⁴ is hydrogen, alkyl, hydroxylalkyl, or haloalkyl; R⁵ is alkyl, hydroxylalkyl, or haloalkyl; and provided that when L is a C₂₋₃ hydrocarbon containing no double bonds and X² is -OR¹, Y¹ is not a bond and Y² is not a bond;

or a salt thereof; and

determining whether the level of acetylated histones in the treated cells is higher than in untreated cells under the same conditions.

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